RULE

Department of Health and Hospitals
Office of the Secretary

Ephedrine Marketing, Advertising, or Labeling
(LAC 48:I.3945)

In accordance with R.S. 49:950 et seq., and pursuant to R.S. 40:962(1) (as enacted by Act 1253 of the 1995 Regular Session of the Louisiana Legislature), the Department of Health and Hospitals, Office of the Secretary hereby adopts rules relative to products containing ephedrine. The statute sets forth the general rule that ephedrine products may be dispensed only by prescription, then enumerates certain exceptions to the general rule.

Title 48
PUBLIC HEALTH—GENERAL
Part I. General Administration
Subpart 1. General

Chapter 39. Controlled Dangerous Substances

§3945. Ephedrine Marketing, Advertising, or Labeling

A. General Rule. Pursuant to the statute, product containing ephedrine may be dispensed only by prescription unless: (a) it is enumerated as an exemption per R.S. 40:962(1)(B) or by the Department of Health and Hospitals review committee, (b) it may be lawfully sold over the counter per the federal Food, Drug and Cosmetic Act, (c) it is labeled and marketed in a manner consistent with OTC Tentative Final or Final Monograph, and (d) is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse. The marketing, advertising, or labeling of any nonprescription product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine for the indication of stimulation, mental alertness, weight loss, appetite control, or energy is prohibited unless the distributor or manufacturer is granted an exemption by the Department of Health and Hospitals.

B. Procedures for Seeking an Exemption

1. Distributors or manufacturers seeking an exemption from the prohibition set forth in Subsection A above must submit documentation which clearly demonstrates the following:

a. the nonprescription product is intended for use for a valid medicinal purpose, and

b. the marketing of the product does not encourage, promote, or abet the abuse or misuse of ephedrine.

2. A review committee composed of representatives from the following groups shall conduct a review of the documentation submitted by the distributor or manufacturer:

a. a pharmacist designated by the Board of Pharmacy,

b. a representative designated by the Board of Wholesale Drug Distributors,

c. a representative designated by the state health officer,

d. a representative designated by the Department of Health and Hospitals, Office of Alcohol and Drug Abuse,

e. a physician designated by the Board of Medical Examiners.

3. The following factors shall be considered by the review committee in determining whether an exemption should be granted, and information related to the factors shall be submitted by the distributor or manufacturer:

a. packaging of the product;

b. name and labeling of the product;

c. manner of distribution, advertising, and promotion of the product;

d. verbal representations made concerning the product; and

e. duration, scope, and significance of abuse or misuse of the particular product.

4. Following a review of the materials submitted by the manufacturer or distributor, the review committee shall report findings and recommendations to the secretary of the Department of Health and Hospitals, who will provide for written notification of the findings and recommendations to the applicant.

AUTHORITY NOTE: Act 1253 of the 1995 Louisiana Regular Legislative Session, enacting R.S. 40: 962(1).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 22: (March 1996).

Bobby P. Jindal
Secretary

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